



DEPARTMENT OF VETERANS AFFAIRS
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December 9, 1999
Mr. Larry Spears
Food and Drug Administration
Office of Compliance
2094 Gaither Rd.
Rockville MD. 20850
Fax (301) 594-4672

In Reply Refer To:

Re: Sterility of Reprocessed Single Use Medical Devices

Dear Mr Spears,

Recently, I learned that the FDA has proposed a new policy to regulate reprocessors of single use medical devices and will hold a "town meeting" on December 14, 1999 in Maryland to receive input on this new policy. Unfortunately, I am unable to attend this meeting but I would like to submit my comments. I strongly support the FDA's efforts to increase regulation of reprocessors of single use medical devices. I do not believe the new FDA policy is sufficient.

I am a registered nurse in charge of the GI Diagnostic Center at DVA Medical Center, San Francisco, California and I am the President of the Northern California Society of Gastroenterology Nurses and Associates. This subject of reusing single use only devices has been under debate in the area of GI for many years. This past year the National SGNA published a Position Statement against the reuse of single use devices. We applaud their position. I am concerned about the potential for patient injury from both the failure of the device as well as the spread of infectious disease. I have read published articles in the US News & World Report, the LA Times and Forbes Magazine that describe actual patient injuries. We at the DVA Medical Centers have been fortunate because the Federal Government regulations does not allow for the reuse of single use medical devices. Any attempt to reclean and reuse such devices is quickly stopped and I strongly support that this practice should continue and be the standard of practice.

Should patients be made aware the these potential problems, I am sure they would object to such devices being used or reused. As a health car provides and patient advocate, I believe it is my duty to speak out on their behalf. The reuse of single use medical devices should be banned. Again, I support your proposed temporary ban, it is the only way to protect the safety of patients.

Sincerely,

Ann Hayes RN, BSN.

Charge Nures GIDC DVA Medical Center, San Francisco

President Northern California Society Gastroenterology Nurses and Associates

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